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PTO IDENTIFIER: **Application Number** 09/743,762-Conf. #7301
Patent Number

Inventor: Cecilia Larsson et al.

MESSAGE TO: US Patent and Trademark Office

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PAGES (Including Cover Sheet): 21

CONTENTS:
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PAGE 1/21 * RCVD AT 10/18/2004 7:03:35 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/2 * DNIS:8729306 * CSID:2022936229 * DURATION (mm-ss):06-06

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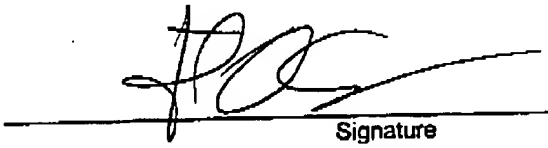

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FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 340.00

Complete if Known	
Application Number	09/743,762-Conf. #7301
Filing Date	May 14, 2001
First Named Inventor	Cecilia Larsson
Examiner Name	W. H. Matthews
Art Unit	3738
Attorney Docket No.	21547-00275-US

METHOD OF PAYMENT (check all that apply)

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	790	2001	395	Utility filing fee	
1002	350	2002	175	Design filing fee	
1003	550	2003	275	Plant filing fee	
1004	790	2004	395	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 0.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below		Fee Paid
Total Claims		-** =		x	=
Independent Claims		-** =		x	=
Multiple Dependent					=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	88	2201	44	Independent claims in excess of 3
1203	300	2203	150	Multiple dependent claim, if not paid
1204	88	2204	44	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge – late filing fee or oath	
1052	50	2052	25	Surcharge – late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	430	2252	215	Extension for reply within second month	
1253	980	2253	490	Extension for reply within third month	
1254	1,530	2254	765	Extension for reply within fourth month	
1255	2,080	2255	1,040	Extension for reply within fifth month	
1401	340	2401	170	Notice of Appeal	
1402	340	2402	170	Filing a brief in support of an appeal	340.00
1403	300	2403	150	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,370	2453	685	Petition to revive - unintentional	
1501	1,370	2501	685	Utility issue fee (or reissue)	
1502	490	2502	245	Design issue fee	
1503	660	2503	330	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37CFR 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($) 340.00

(Complete if applicable)

SUBMITTED BY					
Name (Print/Type)	John A. Evans	Registration No. (Attorney/Agent)	44,100	Telephone	(202) 331-7111
Signature				Date	October 18, 2004

382125

Docket No.: 21547-00275-US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Cecilia Larsson et al.	
Serial No.: 09/743,762	Art Unit: 3738
Filed: May 14, 2001	Examiner: Matthews, William H.
For: Material for Bone Reconstruction	Atty Docket: 21547/00275

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 41.37(a), this brief is filed within two months of the Notice of Appeal filed in this case on August 18, 2004, and is in furtherance of said Notice of Appeal.

The fees required under § 41.20(b)(2), and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1206:

I. Real Party In Interest
II. Related Appeals and Interferences
III. Status of Claims
IV. Status of Amendments
V. Summary of Claimed Subject Matter
VI. Grounds of Rejection
VII. Arguments

1. **Whether the combination proposed by the Examiner meets each claim recitation of the present invention.**

2. **Whether the prior art would have suggested to one of ordinary skill in the art that they should make the claimed composition.**

3. **Whether the prior art would have suggested to those of ordinary skill in the art that the proposed combination carried a reasonable expectation of success.**

4. **Whether the combination suggested by the Examiner forms an inoperable combination and therefore teaches away from the invention.**

5. **Conclusion.**

VIII. Claims Involved in the Appeal (Appendix A).
IX. Evidence.
X. Related Proceedings.
Appendix A. Claims.

I. Real Party in Interest.

The Real Party in Interest is:

Nobel Biocare AB, P.O. Box 5190, S-402, 26, Goteborg, Sweden.

II. Related Appeals and Interferences.

There are no other appeals or interferences known to Appellant, Appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's Decision in this Appeal.

III. Status of Claims

Claims 1-56 were presented.

Claims 1-30 were cancelled

Claims 31-56 are pending in the application.

Claims 31-56 were rejected and are the subject of this appeal.

IV. Status of Amendments.

No amendments were presented following the final rejection issued May 28, 2004.

V. Summary of Claimed Subject Matter.

The invention relates to a material for bone reconstruction. The present invention specifically relates to a preparative material for restoring bone in the body of humans or animals in connection with an existing structure, a bone implant, or some other prosthetic construction. The present invention further relates to a method for restoring bone.[1]

The bone restoring preparation is an easily handleable and controllable preparation (composition) adapted to be applied in the position where bone must be replaced, reinforced. or built up, particularly in connection with a bone implant or some other prosthetic construction where the volume of existing bone is insufficient, or where the quality of the bone is too poor to allow a load carrying function, for example permanent fixing of an implant.[2] In the present context, "easily handleable" means that the inventive composition is readily emplaceable by syringe[3] and readily mouldable.[4]

In context of the present invention, the term "bone implant" means, for instance, a helical, bone-anchored implant of titanium or a titanium alloy, a so-called fixture, but also comprises other types of implant intended to be installed in bone tissue including bone from humans, especially particulated bone, but also in combination with large cortical and/or spongious bone transplants.[5]

There is a great need for the ability to apply an easily accessible safe preparation for restoring bone in connection with implant treatment of patients having an insufficient volume of bone and/or too poor bone quality. An object of the invention is to provide a preparation for restoring bone, which enables implant treatment for patients in various situations especially in areas that otherwise cannot be treated and/or have a poorer prognosis.[6]

Calcium phosphate compounds are biocompatible materials, i.e. materials which are mildly reactive with the environment, promote bone repair, and the integration of implants The most common form of calcium phosphate used to stimulate ossification is hydroxylapatite (HA: $Ca_{10}(PO_4)_6(OH)_2$), but also other compounds containing calcium and phosphate ions exist and resemble the inorga-

[1] Page 1, lines 1-4 (page and line numbers relate to PCT publication WO 00/04940, the priority document of the present application).
[2] Page 1, lines 5-12.
[3] Page 14, lines 5-7.
[4] Page 13, lines 22-23.
[5] Page 1, lines 14-20.
[6] Page 3, lines 20-20.

nic ingredients in skeleton and enamel. Stoichiometric HA, $Ca_{10}(PO_4)_6(OH)_2$, with a Ca:P ratio of 1.67 is seldom found in vivo. Calcium is to some extent replaced by other ions, such as magnesium, sodium, aluminium, strontium, carbonate, fluorine and chlorine, depending on, inter alia, age, food, sex etc. of the individual. HA may be present in a ceramic and in a nonceramic form where the degree of crystallinity may vary depending on the temperature at which the calcium phosphate compound is prepared.[7]

The present invention provides calcium phosphate granules admixed with lipids. Lipids can be divided into different classes. Triglycerides are the most frequent class of lipids and are an important depot of energy in cells. Triglycerides are either built up or decomposed in the body by the intermediary of diglycerides from or into monoglycerides and fatty acids. The body also contains different types of membrane lipids, for example phosphatidyl choline, phosphatidyl ethanolamine, sphingomyelin, cholesterol, mono- and digalactosyldiacylglycerol.

Phospholipids can be prepared fully synthetically but also be cleaned of biological raw materials such as plants or animals. Examples of raw materials are egg yolk, vegetable oils such as soybean oil, rapeseed oil. It is also preferred for the preparation to contain antioxidants selected according to known principles or naturally occurring. An example of an advantageous antioxidant in this case can be tocopherol.[8]

According to the invention, the preparation for restoring bone is a mixture of resorbable calcium phosphate granules and/or a carrier of a biopolymer or lipid type, where the lipid contains an esterified fatty acid selected from the group consisting of triglycerides, diglycerides or phospholipids or combinations thereof. The invention aims at overcoming the difficulties described above and constituting a preparation which easily and in a repetitive manner can be used in connection with bone implants. More specifically, the inventive material is intended to withstand dilution and transporting away from the area of application. Such a mixture can be given the "correct" consistency depending on the type of application, it can be made, for example, mouldable, and it is easy to handle, control and apply.[9]

The preparation for restoring bone consists of a mixture of resorbable calcium phosphate granules and a carrier of a biopolymer or lipid type. To be applied in connection with a bone implant and be kept in the area of application, it is important for the mixture to be mouldable and to have the correct consistency. If

[7] Page 3, line 32 - Page 4, line12.
[8] Page 5, line 26 – page 6, line 7.
[9] Page 9, lines 4-18.

the particles are transported away from the area of application, they could cause irritation or complications in other positions in the body.[10]

VI. Grounds of Rejection.

Claims 31-40, 43-50, 52-54, and 56 were rejected under 35 U.S.C. § 103(a) as being unpatentble over NGK Spark Plug (NGK) (JP 2 198 560) in view of Cassidy (US 6,280,474).

Claims 41, 42, 51, and 55 were rejected under 35 U.S.C. § 103(a) as being unpatentble over NGK Spark Plug (NGK) (JP 2 198 560) in view of Cassidy (US 6,280,474), as above, and further in view of Larsson (US 5,196,201).

VII. Arguments.

Rejection of claims 31-40, 43-50, 52-54, and 56 under 35 U.S.C. § 103(a) over NGK Spark Plug (NGK) (JP 2 198 560) in view of Cassidy (US 6,280,474).

Rejection of claims 41, 42, 51, and 55 under 35 U.S.C. § 103(a) over NGK Spark Plug (NGK) (JP 2 198 560) in view of Cassidy (US 6,280,474) and further in view of Larsson (US 5,196,201).

The claims on appeal, which are co-extensive with the pending claims comprise independent Claim 31 and dependent Claims 32-56. Claim 31 recites:

> A bioresorbable and biocompatible composition for restoring bone in the body of a human or other animal, said composition comprising: calcium phosphate granules; lipid; and hyaluronic acid; wherein said composition forms a moldable, injectable mass upon admixture with water, and wherein said composition is resorbable by said body.

The recitations of Claim 31 at least include, but are not limited to: a bioresorbable composition, calcium phosphate granules, and the properties of moldability and injectability.

As an initial threshold, to establish *prima facie* obviousness of a claimed invention, all the claim recitations must be taught or suggested by the prior art. *In re Royka.*[11] All words in a claim must be considered in judging the patentability of that

[10] Page 10, lines 15-24.
[11] *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

claim against the prior art. *In re Wilson.*[12] When evaluating the scope of a claim, every recitation in the claim must be considered. See e.g. *In re Ochiai.*[13] The evidentiary record fails to teach each recitation of the present invention. Furthermore, Appellant submits that the threshold issue includes whether the examiner has carried the legal burden to establish a case of *prima facie* obviousness against Appellant's claimed composition. In other words, do the cited references motivate a skilled worker to select and combine the various agents into a single analytical composition with a reasonable expectation that if this were done, a successful result would be obtained? For at least the reasons detailed below, Appellant respectfully submits that the examiner has not met that burden. First, the alleged *prima facie* case fails to teach each recitation; and second, the cited art fails to provide the person of skill in the art the requisite motivation to try the proposed combination, nor does the art provide the required reasonable expectation of success. Therefore, no case of *prima facie* obviousness has been established against the claims. Accordingly, the rejections are improper and should be withdrawn.

Whether the combination proposed by the Examiner meets each claim recitation of the present invention.

NGK does not teach the recitation "calcium phosphate." Claim 31 recites "calcium phosphate" which the specification specifically defines to be a hydroxylated material ($Ca_{10}(PO_4)_6(OH)_2$). NGK relates to a ceramic composition formed by firing calcium phosphate at 1100°C.[14] As is known in the art, firing calcium phosphate compositions at high temperatures gives rise to a glass-ceramic product and not calcium phosphate granules. For example, Manabe, et al. disclose the formation of a calcium phosphate glass by heating to temperatures of from 200 to 900°C and then from 900 to 1500°C.[15] Barlow, et al. teach that high-temperature processing of calcium

[12] *In re Wilson*, 424 F.2d 1382, 165 USPQ 494, (CCPA 1970).
[13] *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995).
[14] NGK (JP 2 631 890) page 14, lines 6-8.
[15] US 5,236,495 (col. 3, line 60 – col. 4, line 2).

phosphate forms a glass-ceramic by removal of water.[16] The specification defines calcium phosphate as would one of skill in the art:

> Calcium phosphate compounds are biocompatible materials, i.e. materials which are mildly reactive with the environment, promote bone repair, and the integration of implants. The most common form of calcium phosphate used to stimulate ossification is hydroxylapatite (HA: $Ca_{10}(PO_4)_6(OH)_2$), but also other compounds containing calcium and phosphate ions exist and resemble the inorganic ingredients in skeleton and enamel. Stoichiometric HA, $Ca_{10}(PO_4)_6(OH)_2$, with a Ca:P ratio of 1.67 is seldom found in vivo. Calcium is to some extent replaced by other ions, such as magnesium, sodium, aluminium, strontium, carbonate, fluorine and chlorine.[17]

Note especially, that as defined by the present invention, calcium phosphate is a hydroxylated (OH) material. However, as is known to the art, the high temperature treatment of NGK forms a material from which the hydroxyls has been removed.

> Although it may be questioned whether high-temperature ceramics are [hydroxylapatite] at all (since high-temperature treatment results in a severely hydroxyl-deficient material).[18]

Although NGK start from a calcium phosphate similar to that recited by the present invention, the art recognizes that the high-temperature process of NGK results in a de-hydroxlyated product that differs from material recited by the present invention.

Neither NGK nor Cassidy teaches "a moldable, injectable mass." NGK relates to a ceramic container for the sustained-release of drugs or other medicials.[19] NGK is ambiguous respecting "injectable," but it is silent as to "moldable." Cassidy explicitly teaches away from each of moldable and injectable. Cassidy relates to a device to be emplaced, by hand, into a broken bone to provide a rigid

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[16] Barlow, J.W., et al., Preparation of Calcium Phosphate Implants, *Global Summit*, Annual Meeting, 2000, Global Alliance of Rapid Prototyping Associations (GARPA), page 3.
[17] Page 3, line 32 - Page 4, line12.
[18] Ricci, JL, Evaluation of Low-Temperature Calcium Phosphate Particulate Implant Material, 50 J. Oral Maxillofac. Surg. 969 (1992).
[19] NGK (JP 2 631 890) page 4, Claim 2.

mechanical anchor. "More specifically, the implants impart enhanced load bearing capacity to hard tissue, which increases the load that can be put on the hard tissue during the repair process."[20] Cassidy further relates to a "dense, pre-formed hard tissue implant."[21] The recitation "dense, pre-formed hard," clearly does not relate to moldable and injectable. Rather, this recitation teaches away from moldable and injectable.

NGK does not relate to a "composition" of calcium phosphate and lipid. Claim 31 recites a composition comprising calcium phosphate granules; lipid; and hyaluronic acid. NGK forms a "green body"[22] by mixing calcium phosphate and a waxy organic material. The waxy binder is subsequently destroyed by heating to 1100°C.[23] the final product is a glass material without the waxy substance. The product of NGK is not composed of lipid. NGK disclose a glass bottle for containing materials which may include lipid or other materials ("liposome containing ceramic body")[24]. However, a container enclosing a lipid is not the same as a "composition" comprising a lipid.

NGK does not disclose a bioresorbable material. Claim 31 recites a "bioresorbable" composition. The NGK glass-ceramic is not bioresorbable. Rather, the "liposome containing ceramic body is recovered after and elution.[25] NGK explicitly provide a recyclable container (the ceramic body can be used "circularly").[26]

Whether the prior art would have suggested to one of ordinary skill in the art that they should make the claimed composition.

"Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under §103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device. [T]he suggestion... must be founded in the prior art, not in the Appellant's disclosure."[27] In the

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[20] Cassidy (6,280,474, col. 8, lines 9-10).
[21] Cassidy (6,280,474, col. 3, lines 18-19).
[22] *See* Barlow, *supra*, page 3, Figure 2.
[23] NGK page 14, lines 2-8.
[24] NGK page 15, lines 31-32.
[25] NGK page 15, lines 31-32.
[26] NGK page 15, lines 37-38.
[27] *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (citation omitted).

case of a patent based on the combination of two known elements, "[t]here is no basis in the law ... for treating combination inventions any different than other inventions." *Fromson v. Advance Offset Plate, Inc.*[28] (holding that the combination of three known separate process steps into a single step is nonobvious); *Brentingson Fishing Equipment Co. v. Shimano American Corp.*,[29] ("the focus under section 103 is not whether each element in a claimed invention is old and unpatentable, but whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination."); *Connell v. Sear, Roebuck & Co.*,[30] ("There is no [separate statutory] classification entitled *combination patents*. Virtually every invention is a combination of elements or process steps.") (emphasis in original)

The court has repeatedly struck down PTO and Board decisions rejecting claims under section 103 where there is no suggestion or motivation in the prior art to combine the teachings of the two or more cited references. This is especially true in the context of combination inventions. In such cases, the court often finds that the PTO and Board improperly asserted a *prima facie* case of obviousness based on the teachings of the Appellant's own disclosure. *In re Rouffet*.[31]

> "As this court has stated, 'virtually all inventions are combinations of old elements.' *** Most, if not all, inventions are combinations and mostly of old elements. Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be 'an illogical and inappropriate process by which to determine patentability.'"
>
> "To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, ... with no knowledge of the claimed invention, would

[28] 755 F.2d 1549, 1556 (Fed. Cir. 1985).
[29] 8 U.S.P.Q. 2d 1669, 1672 (Fed. Cir. 1988).
[30] 722 F.2d 1542, 1549 (Fed. Cir. 1983).
[31] 149 F.3d 1350 (Fed. Cir. 1998).

> select the *elements* from the cited prior art references *for combination in the manner claimed.*" (emphasis added)

The Court in *Rouffet* tells us that one skilled in the art must be motivated by some teaching in the references to make the specific combination claimed. *See*, also *In re Dembiczak* [32] ("the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then accepted wisdom in the field.").

The combination of two known components to make a novel composition has been held by the court to be non-obvious. *In re Jones*.[33] In *Jones*, the court reversed the Board's decision rejecting the claims as prima facie obvious because the Board failed to identify any suggestion in the cited references, or in the knowledge generally available, to combine the two components in a single composition. The invention was directed to the combination of dicamba (a substituted benzoic acid) and a specific ammonium cation derived from the amine, 2-(2'-aminoethoxy) ethanol. The primary reference broadly disclosed substituted ammonium salts of dicamba. The secondary reference disclosed the claimed ammonium cation for use with various surfactants. However, nowhere in the art was the specific combination of the two agents ever suggested. The court went on to state: "Conspicuously, missing from the record is any evidence, other than the PTO's speculation (if it be called evidence) that one of ordinary skill in the herbicidal art would have been motivated to make the modifications of the prior art salts necessary to arrive at the claimed 2-(2'-aminoethoxy) ethanol salt." [34] *Id.* at 351.

The present invention teaches a composition formed from calcium phosphate granules, lipid, and hyaluronic acid. The Examiner explicitly acknowledges NGK to lack written disclosure of a glycosaminoglycan, such as hyaluronic acid. The Examiner alleges that NGK discloses the claimed form, but not the specific diameter, of calcium phosphate. According to the Examiner, Cassidy supplies the lacking recitations. As discussed above, NGK relates to a dehydroxylated form of calcium phosphate, formed at

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[32] 50 U.S.P.Q. 2d 1614 (Fed. Cir. 1999).
[33] 958 F.2d 347 (Fed. Cir. 1992).
[34] 958 F.2d 351.

high temperatures, and does not relate to the hydroxylated form disclosed in the present invention. A person of skill would not have been motivated to combine the hyaluronic acid of Cassidy to form the pre-fired "green body" of NGK, because the expensive hyaluranic acid would be destroyed by the high temperatures used by NGK.

The Federal Circuit's admonition that combinations of old elements (*i.e.*, elements *per se* taught in the art even for the same purpose as claimed) can still be patentable was restated in *The Gillette Company v. S. C. Johnson & Son, Inc.*[35]:

> It is true that [the claimed invention] consists of a combination of old elements so arranged as to perform certain related functions. It is immaterial to the issue, however, that all of the elements were old in other contexts. *What must be found obvious to defeat the patent is the claimed combination.*

And the Court carefully distinguished the legal standard of obviousness from "obvious to try":

> [a]n "obvious-to-try" situation exists when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued. *** However, we have consistently held that "obvious to try" is not to be equated with obviousness under 35 USC 103.

See also In re Fine, [36](no *prima facie* obviousness; "obvious to try" is "not a legitimate test of patentability"); and *In re Tomlinson*,[37] (patentability determinations based upon obviousness to try is contrary to the statutory standards under 103).

Whether the prior art would have suggested to one of ordinary skill in the art that the proposed combination carried a reasonable expectation of success.

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[35] 15 U.S.P.Q.2d 1923 (Fed. Cir. 1990)
[36] 5 U.S.P.Q.2d 1596, 1598-9 (Fed. Cir. 1988).
[37] 363 F.2d 928 (C.C.P.A. 1966).

A proper analysis under §103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the Appellant's disclosure." [38]

The teachings of NGK and Cassidy conflict, such that a person of skill in the art would not have a high expectation that their combination would be successful. It is possible to combine the calcium phosphate of NGK with the hyaluronic acid of Cassidy. However, because the hyaluronic acid is destroyed by the high temperatures of the NGK method, a person of skill would have no expectation that a composition comprising hyaluronic acid could successfully be formed.

Whether the combination suggested by the Examiner forms an inoperable combination and therefore teaches away from the invention.

Where the Examiner proposes a combination that makes a prior art reference inoperable for its intended purpose, the resulting inoperable prior art reference is considered to teach away from the proposed combination, thereby supporting a showing of nonobviousness. *In re Gordon*,[39] (finding no suggestion to modify a prior art device where the modification would make the device inoperable for its intended purpose); *TecAir, Inc. v. Denso Mfg. Michigan Inc.*,[40] (holding that because the combination was inoperable for its intended purpose, a jury could reasonably find the patent taught away from the combination); *In re Sponnoble*,[41] (holding if where combined, the references

[38] *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (citation omitted).
[39] 733 F.2d 900, 902 (Fed. Cir. 1984).
[40] 192 F.3d 1353, 52 USPQ 2d 1294, 1298 (Fed. Cir. 1999).
[41] 405 F.2d 578, 587 (CCPA 1969).

would produce a seemingly inoperative device, the references teach away from their combination).

As analyzed above, the combination of NGK and Cassidy is inoperable. As is known to persons of skill, exposing organic materials, of the type disclosed by Cassidy, to temperatures of 1100°C suffices to destroy them. Therefore, the organic material would not be available to participate in the composition of Cassidy. Nor would they be available to the present invention.

Rejection of claims 41, 42, 51, and 55 under 35 U.S.C. § 103(a) over NGK Spark Plug (NGK) (JP 2 198 560) in view of Cassidy (US 6,280,474) and further in view of Larsson (US 5,196,201).

In view of the dependence of Claims 41, 42, 51, and 55 on Claim 31, the Appellant realleges and specifically incorporates by reference each argument advanced in support of the patentability of Claims 31-40, 43-50, 52-54, and 56.

The Examiner cites Larsson as teaching specific lamellar phase lipids as recited by the present invention. However, Larsson does not support the *prima facie* case because the lipids of Larsson would be destroyed by the high temperatures of NGK.

Conclusion.

The mere fact that prior art may be modified in the manner suggested by the Examiner does not make this modification obvious, unless the prior art suggests the desirability of the modification. No such suggestion appears in the prior art in this matter. The Examiner's attention is kindly directed to *In re Gordon*,[42] ; *In re Laskowski*;[43] and *In re Fritch*.[44]

Concerning the above rejection of the claims, the Examiner should be mindful of the following cautionary statement made by the Court in *Grain Processing Corp. v. American Maize-Products Corp.*[45] :

> Care must be taken to avoid hindsight reconstruction by using the patent in suit as a guide through the maze of prior art references, combining the

[42] 221 USPQ 1125 (Fed. Cir. 1984).
[43] 10 USPQ2d 1397 (Fed. Cir. 1989).
[44] 23 USPQ2d 1780 (Fed. Cir. 1992).
[45] 5 USPQ2d 1788 (Fed. Cir. 1988).

> right references in the right way so as to achieve the same result of the claims in suit.

Likewise, as stated by the court in *Interconnect Planning Corp. v. Feil*:[46]

> It is error to reconstruct the patentee's claimed invention from the prior art by using the patentee's claim as a blueprint. When prior art references require selected combination to render obvious a subsequent invention, there must be some reason for the combination, other than the hindsight obtained from the invention itself. It is critical to understand the particular results achieved by the new combination.

In the present situation, no such reasoning for the combination exists in the prior art, and nothing in the prior art would suggest the properties achieved by the present invention. Also, see *In re Fine*,[47] wherein the Court stated that "one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." Moreover, it is important to keep in mind that statements in the prior art should not be read out of context when evaluating obviousness. See *In re Wright*.[48]

The prior art lacks the necessary direction or incentive to those of ordinary skill in the art to render a rejection under 35 USC 103 sustainable. The prior art fails to provide the degree of predictability of success of achieving the properties attained by the present invention needed to have a rejection under 35 U.S.C. 103 sustained. See *In re Mercier*,[49] and *In re Naylor*.[50]

Moreover, the properties of the subject matter and improvements which are inherent in the claimed subject matter and disclosed in the specification are to be considered when evaluating the question of obviousness under 35 USC § 103. See *Gillette Co. v. S.C. Johnson & Son, Inc.*;[51] *In re Antonie*;[52] *In re Estes*;[53] and *In re Papesch*.[54]

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[46] 227 USPQ 543 (Fed. Cir. 1985).
[47] 5 USPQ2d 1596 (Fed. Cir. 1988).
[48] 9 USPQ2d 1649 (Fed. Cir. 1989).
[49] 187 USPQ 774 (CCPA 1975).
[50] 152 USPQ 106 (CCPA 1966).
[51] 16 USPQ2d 1923 (Fed. Cir. 1990).
[52] 195 USPQ 6 (CCPA 1977).
[53] 164 USPQ 519 (CCPA 1970).
[54] 137 USPQ 43 (CCPA 1963).

No property can be ignored in determining patentability and comparing the claimed invention to the prior art. Along these lines, see *In re Papesch*, supra, *In re Burt et al.*;[55] *In re Ward*;[56] and *In re Cescon*[57].

VIII. Claims Involved In The Appeal.

A copy of the claims involved in the present appeal is attached hereto as Appendix A.

IX. Evidence.

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered or relied upon by the Examiner is being submitted.

X. Related Proceedings.

No proceedings relevant to the present appeal are involved, hence no Appendix is included.

Conclusion.

The above discussion renders it abundantly clear that the Primary Examiner erred in finally rejecting claims 31-56. Therefore, the undersigned respectfully requests the Board to reverse the Examiner and grant claims 31-56.

Respectfully submitted,

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[55] 148 USPQ 548 (CCPA 1966).
[56] 141 USPQ 227 (CCPA 1964).
[57] 177 USPQ 264 (CCPA 1973).